

FEB 01 2002

510(k) SUMMARY

December 11, 2001

CONTACT:

Douglas L. Harris
Greiner Vacuette North America, Inc.
P.O. Box 1026
Monroe, NC 28111

K014104

NAME OF DEVICE:

Trade Name: Vacuette® EDTA K2 Tubes
Common Names/Descriptions: Evacuated Blood Collection System
Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection

PREDICATE DEVICE:

Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube (K972075)

DEVICE DESCRIPTION:

INTENDED USE: The **VACUETTE®** EDTA K2 tube provides a means for collection, processing and transportation of an undiluted plasma specimen in a closed evacuated system. The tube contains spray-dried EDTA, yielding a ratio of 1.8mg/mL of blood when the evacuated tube is filled correctly to its fill volume.

PRODUCT DESCRIPTION: The **VACUETTE®** EDTA K2 Tube is used for plasma preparation and is made of plastic for the collection of venous blood which upon centrifugation separates undiluted plasma for use in molecular diagnostic test methods (such as but not limited to PCR – Polymerase Chain Reaction), or other procedures where an undiluted plasma specimen is required as determined by the laboratory.

SUBSTANTIAL EQUIVALENCE:

The **VACUETTE®** EDTA K2 Tube and the Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube are substantially equivalent in intended use, design and composition.

Studies were conducted to demonstrate substantial equivalence of the Greiner **VACUETTE®** EDTA K2 Tube to the Becton Dickinson (BD) Vacutainer® Brand PPT™ Plasma Preparation Tube when samples from these tubes are used in PCR assays.

The substantial equivalence studies included:

- Limited validation testing on the HIV and HCV PCR assays using WHO standards at the lower detection limits; comparison of HIV and HCV lower detection limits using both types of tubes;
- Comparison of HIV and HCV recovery using both types of tubes;
- Equivalency studies of Greiner and BD tubes with regard to results of HIV and HCV PCR testing;
- Evaluation of effects of delay in separation of plasma and blood cells on HIV and HCV results using both types of tubes;
- Determination of equivalency of HIV and HCV results from fresh and multiple freeze/thaw samples collected in the two tube types.

The conclusions from the study were:

- Both tubes demonstrated similar sensitivity and recovery at the lower detection limits for both HIV and HCV quantitation;
- Both tubes demonstrated substantially equivalent results in HIV and HCV quantitation;
- No effect was seen when plasma collected from the Greiner tube was separated from blood cells within 24 hours for HIV or within 2 hours for HCV;
- There was no difference in HIV or HCV results within or between the two tube types for fresh versus once frozen samples or when plasma samples were exposed to 5 freeze/thaw cycles for HIV or HCV.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Sienna Partners, L.L.C.
Judi Smith
Principal
P. O. Box 103
Baldwin, MD 21013

FEB 06 2015

Re: k014104
Trade/Device Name: Vacuette EDTA K2 Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: PJE
Dated: December 11, 2001
Received: December 13, 2001

Dear Ms. Smith:

This letter corrects our substantially equivalent letter of February 1, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809J), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note

the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for : Courtney H. Lias, Ph.D.

Director

Division of Chemistry and Toxicology Devices

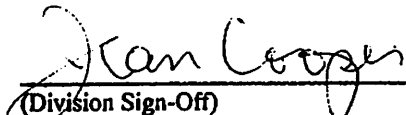
Office of In Vitro Diagnostics and Radiological Health

Center for Devices and Radiological Health

510(k) Number (if known): K014104

Device Name: **VACUETTE®** EDTA K2 Tubes

Indications For Use: The **VACUETTE®** EDTA K2 tube provides a means for collection, processing and transportation of an undiluted plasma specimen in a closed evacuated system. The tube contains spray-dried EDTA, yielding a ratio of 1.8mg/mL of blood when the evacuated tube is filled correctly to its fill volume. The **VACUETTE®** EDTA K2 tube is used for plasma preparation and is made of plastic for the collection of venous blood which upon centrifugation separates undiluted plasma for use in molecular diagnostic test methods (such as but not limited to PCR – Polymerase Chain Reaction), or other procedures where an undiluted plasma specimen is required as determined by the laboratory.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014104

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)